

SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE

RE: DOCUMENT NUMBER K032868

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II devices. The following items are present and acceptable:

1. The name and 510(k) numbers of the SUBMITTER'S previously cleared devices. This 510(k) was received and reviewed under the policy for bundling and contains information for 11 separate assays:

K022992 REAADS anti-Cardiolipin IgG/IgM Semi-Quantitative Test Kit (2 assays)

K022990 REAADS IgA anti-Cardiolipin Semi-Quantitative Test Kit

K024196 REAADS anti-Phosphatidylserine IgG/IgM Semi-Quantitative Test Kit (2 assays)

K024195 REAADS IgA anti-Phosphatidylserine Semi-Quantitative Test Kit

K031208 REAADS IgG anti-Beta 2 Glycoprotein I Semi-quantitative Test Kit

K031208 REAADS IgM anti-Beta 2 Glycoprotein I Semi-Quantitative Test Kit

K031208 REAADS IgA anti-Beta 2 Glycoprotein I Semi-Quantitative Test Kit

K031208 REAADS IgG anti-Prothrombin Semi-Quantitative Test Kit

K031208 REAADS IgM anti-Prothrombin Semi-Quantitative Test Kit

2. Submitter's statement that the **INDICATIONS/INTENDED USES** of the modified devices as described in their labeling **HAVE NOT CHANGED** along with the proposed labeling which includes instructions for use and package labeling. (*page 12 or 13 of each analyte section*)
3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified devices **has not changed**. (*page 3 or 4 of each section*)

The changes were to 1) to increase the assay incubation periods from 15 minutes, 15 minutes and 10 minutes to 30-40 minutes per incubation period; and 2) to allow an air blank method of zeroing the plate reading equipment, rather than a water blank.

The sponsor also requested the ability to separate the combined IgG/IgM kits into individual isotypes (separate IgG and IgM kits).

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate devices including, labeling, intended use and physical characteristics. (*pages 5-12 of each section*)

5. **A Design Control Activities Summary** which includes:
- a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the devices and their components, and the results of the analysis (*pages 13-14 of each section*);
 - b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied (*page 13-14 of each section*);
 - c) A declaration of conformity with design controls. The declaration of conformity should include:
 - i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met (*pages 41 or 42 of each section*) and
 - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review (*pages 41 or 42 of each section*).
6. **Truthful and Accurate Statements** (*pages 42-46*), **510(k) Statements** (*pages 40-44*) and **Indications for Use Enclosures** (*pages 36-40*).

The labeling for these modified subject devices has been reviewed to verify that the indication/intended use for the devices are unaffected by the modifications. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, we recommend the devices be determined substantially equivalent to the previously cleared (or their preamendment) devices.

(Reviewer's Signature)

(Date)

(Reviewer's Signature)

(Date)